U.S. FOOD & DRUG ADMINISTRATION

By Electronic Mail

August 8, 2022

Terry Hill
Stability Biologics, LLC
1077 Central Pkwy S., Suite 500
San Antonio, Texas 78232
thill@stabilitybio.com

RE: Request for Recommendation for AmnioCore Amniotic Membrane Sheets

Dear Dr. Hill:

This letter is in response to your inquiry provided to the Food and Drug Administration's Tissue Reference Group (TRG) on March 4, 2022. You are seeking a recommendation from the TRG whether your AmnioCore Amniotic Membrane Sheets, that appear to be human cells, tissues, or cellular or tissue-based products (HCT/Ps), are regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271.

Your submission describes processing amniotic membrane that includes rinsing, disinfection, drying, cutting, and sterilization with irradiation. The amnion may be folded for a multiple layer sheet or left unfolded for a single layer sheet and the smallest product size is a 16 mm disc. You describe the AmnioCore Amniotic Membrane Sheets as intended for use "as a barrier" and "applied only as a covering to offer protection from the surrounding environment."

An HCT/P is regulated solely under section 361 of the PHS Act and the regulations in part 1271, if the HCT/P meets all four criteria at 21 CFR 1271.10(a)[1]. Based on the description you provide of the processing steps and the minimum size of the products, AmnioCore Amniotic Membrane Sheets, when intended for use as a barrier and as a covering, appear to meet all the criteria for regulation solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

This recommendation applies solely to the AmnioCore Amniotic Membrane Sheets described in your submission of March 4, 2022, when intended for use as a barrier and as a covering. This recommendation does not apply to any other AmnioCore branded products manufactured or marketed by Stability Biologics, LLC. We are also aware of Stability Biologics, LLC's application to the Centers for Medicare & Medicaid Services for the "AmnioCore™" product[2].

[1] The four criteria can be found at 21 CFR 1271.10(a), and, as applicable, see the following guidance documents: "Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff" dated July 2020; and, "Same Surgical Procedure Exception under 21 CFR 1271.15(b): Questions and Answers Regarding the Scope of the Exception; Guidance for Industry" dated November 2017.

[2] "Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions First Quarter, 2020 Coding Cycle for Drug and Biological Products".

Please note that this recommendation is based on the information you provided. Any variation from what you describe in your request for recommendation to the TRG, including but not limited to changes in the processing or proposed use, may raise additional regulatory considerations that could impact the applicability of this recommendation. For example, an amniotic membrane product, when intended for wound healing and/or to reduce scarring and inflammation would not be considered a homologous use because wound healing and reduction of scarring and inflammation are not basic functions of amniotic membrane[3].

For questions regarding this response letter, please contact the Executive Secretary for the TRG at TissueReferenceGroup@fda.hhs.gov.

Sincerely,

Wilson Bryan -S

Digitally signed by Wilson Bryan -S
Date: 2022.08.04 13:50:32 -04'00'

Wilson W. Bryan, M.D.
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

James P. Bertram -S

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James Bertram, Ph.D.
Associate Director
Regulatory Policy and Combination Products Staff
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[3] See Example 19-4 in "Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use; Guidance for Industry and Food and Drug Administration Staff" dated July 2020.